

- Application No. 09/513,888
- Reply to Office Action of August 26, 2003

REMARKS

Claims 23, 24, 100-157 are pending in the application.

Claims 23 and 24 have been found allowable by the Examiner in prior Office Actions.

New claims 145 to 157 have been added. Support for the new claims is found at least in claims 1-99 as originally filed, and the specification at pages 3, 11, 19, and 21-24 and Figures 11-14.

Claims 120 to 121 and 142 have been amended. No new matter is added by the amendment.

I. Rejection Under 35 U.S.C. § 112 - Enablement.

The Examiner has maintained the rejection of claims 118-121, 141, 142, and 144 under 35 U.S.C. § 112, first paragraph. The Examiner maintains that such rejection is directed to a process of gene therapy and that such "gene therapy" is known in the art to be unsuccessful. Therefore, the Examiner considers that the claims are not enabled.

The applicants again traverse the rejection, and request that it not be applied to the new claims.

The applicants traverse this rejection on the basis provided in its prior responses, each of which is incorporated herein. The applicants maintain that a person of ordinary skill in the relevant art, based upon the disclosure provided in the specification and given the sequences of peptides and/or nucleic acid molecules provided in the application, would find it well within the purview of routine skill to prepare and use polynucleotides, and pharmaceutical compositions of the invention as claimed. However, this response addresses primarily only the points raised by the Examiner in Paper No. 30.

The Examiner bases his conclusion on the findings of fact he has made with respect to each factor. The applicants point out that the Examiner has in most cases, failed to provide any evidence underpinning his finding of facts, nor has he in all cases addressed the applicants' rebuttal arguments. For example, the applicants maintain that the claims are not broad, as they recite specific polynucleotide sequences. The Examiner has made no comment other than his initial conclusory statement that the claims are broad.

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The Examiner has noted that the applicants submitted references in Paper No. 38 to rebut the applicants' statement that there is "a complete lack of documented success for any gene therapy." However, while conceding that those references indicate that some types of gene therapy have achieved some degrees of success, the Examiner has impermissibly declined to consider this information, asserting that it is too difficult to judge the degree of "success" in the references, and that it is not possible to determine whether the references shed any light on which cancers might be specifically correlated with FEZ1 activity. The Examiner's position serves only to highlight the fact that even those references provided by the Examiner in his initial rejection cannot serve to demonstrate that all gene therapy is ineffective and therefore cannot serve as evidence that the entire technology is unpredictable. Thus, it has been demonstrated that the Examiner's conclusion of gene therapy's alleged absolute infeasibility to be not supported by the state of the art at the time the invention was filed, as evidenced by the art cited by the applicants.

Moreover, despite the Examiner's protestations to the contrary, the level of skill in the relevant art is inextricably linked to the determination of whether any necessary experimentation is undue or routine. Such assessments are, as a matter of law, always made in view of the level of skill of a person of ordinary skill in the relevant art. Thus, when one finds as the Examiner has in this case, that the level of a person of ordinary skill in the art is high, both logic and law dictate that the level of complexity of experimentation may be greater. See, e.g., *Nat'l Recovery Technologies, Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190 (Fed. Cir. 1999). ("[W]ith respect to enablement, the relevant inquiry lies in the relationship between [sic] the specification, the claims, and the knowledge of one of ordinary skill in the art.")

Accordingly, for at least the reasons discussed above and those provided in the prior responses, the applicants assert that the claims are fully enabled as required by 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of the rejection is requested.

II. Rejection Under 35 U.S.C. § 112, First Paragraph - Written Description.

The Examiner has maintained the rejection of claims 100-143 under 35 U.S.C. § 112, first paragraph asserting that the claims fail to comply with the written description requirement. In particular, he contends that the specific "subsets" of the polynucleotide residues recited in the

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claims was not expressly written out in the specification, and therefore the claims contain new matter.

The applicants again traverse the rejection and request that it not be applied to the new claims.

The portions of SEQ ID NO: 1 identified by the arbitrarily assigned polynucleotide residue number as recited in, *e.g.* claim 1, do not constitute new matter. The standard for assessing whether a claim has incorporated new matter is whether or not, based upon the originally filed specification, a person of skill in the art would have understood that the invention was in possession of the invention. In the present case there is no question that the applicants were in possession of the invention. The entire length of SEQ ID NO: 1 is laid out, residue by residue, in the original specification. *See, e.g.* SEQ ID NO: 1. The application further teaches that portions or fragments of SEQ ID NO: 1 may be used in any of the various applications taught and discussed in the specification. Moreover, as is known to a person of skill in the art long polynucleotide sequences are routinely truncated, spliced, snipped, or otherwise manipulated into “subset” polynucleotide molecules in order to fulfill the various needs or requirements of the manipulator, such as use as primers. Thus, a person of ordinary skill in the art would have understood that the applicants were in possession of any consecutive polynucleotide “subset” molecule that exists within the larger polynucleotide molecule of SEQ ID NO: 1.

The Examiner is improperly applying the new matter principles related to ranges for example of temperature, or of quantity, etc., when the specification contains no disclosure of the intervening subsets. In each of those cases, the specifications did not recite any of the intervening temperature points. In contrast, this specification as originally filed contained each and every polynucleotide residue of SEQ ID NO: 1. Therefore, a person of ordinary skill in the art would have understood that the applicants were fully in possession of the invention at the time it was filed.

It is requested that the Examiner reconsider and withdraw the rejection based upon 35 U.S.C. § 112, first paragraph, for lack of written description.

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III. Rejection Under 35 U.S.C. § 101.

The Examiner has rejected claims 120, 121 and 142 under 35 U.S.C. § 101 asserting that the claimed invention is directed to non-statutory subject matter. In view of the amendments made to these claims, it is submitted that this rejection is no longer applicable. Reconsideration and withdrawal of the rejection is respectfully requested.

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CONCLUSION

In view of the foregoing, it is submitted that claims 23, 24, 100-157 are fully compliant with the statutory requirements of patentability. Therefore, reconsideration and allowance of the claims at the earliest opportunity is respectfully requested.

Respectfully submitted,

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(Date)

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